K042941

DEC - 2 2004

510(k) Summary
Heparin Calibrator and Controls

1. Manufacturer's Name, Address, Telephone, and Contact Person, Date of Preparation:

Manufacturer: Dade Behring Inc.
P.O. Box 6101
Newark, Delaware 19714

Contact Information: Dade Behring Inc.
P.O. Box 6101
Newark, Delaware 19714
Attn: Radames Riesgo
Tel: 305.480.7558

Preparation date: October 22, 2004

2. Device Name/ Classification:

Dade Behring Heparin Calibrator and Controls / Multipurpose system for in vitro coagulation studies, Class II (864.5425)

3. Identification of the Legally Marketed Device:

aca® Heparin Calibrator (K843202)

Ci-Trol® Heparin Controls, Low and High (K812424)

4. Device Description:

Dade Behring Heparin Calibrator and Controls are lyophilized products prepared from citrated human plasma and contain unfractionated heparin from a porcine source. The kit consists of a calibrator and two levels of assayed controls intended to monitor the performance of Berichrom® Heparin reagent when testing for unfractionated heparin using coagulation analyzers.

5. Device Intended Use:

The Dade Behring Heparin Calibrator is an *in vitro* diagnostic product used to calibrate the Berichrom® Heparin assay for the measurement of unfractionated heparin. Dade Behring Heparin Controls are *in vitro* diagnostic products intended to be used as assayed, unfractionated heparin quality control materials for the Berichrom® Heparin assay.

6. Medical device to which equivalence is claimed and comparison information:

The Heparin Calibrator is substantially equivalent in intended use to Dade Behring aca® Heparin Calibrator, Level 3 (K843202). The Controls are substantially equivalent to Dade Behring Ci-trol® Heparin Controls, Low and High (K812424).

7. Device Performance Characteristics:

Using at least duplicate determinations, reconstituted stability data met the acceptance criteria of recovering within the assigned values when stored for eight (8) hours at 2 to 8°C.

Different dilutions of USP Heparin Sodium Reference Standard were spiked into citrated plasma samples and the heparin recovery evaluated using a calibration curve established using the USP Heparin Sodium Reference Standard. The same samples were then measured using a calibration curve established with the new Heparin calibrator. Results were compared using regression analysis and the following statistics were obtained:

Dade Behring BCS® Analyzer: $Y = 1.07 X - 0.01$, $r = 0.9985$
Sysmex® CA-1500 Analyzer: $Y = 0.97 X + 0.01$, $r = 0.9996$

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Mr. Radames Riesgo
Manager, Regulatory Affairs and Compliance
Dade Behring, Inc.
Glasgow Site
P.O. Box 6101
Newark, Delaware 19714

DEC - 2 2004

Re: k042941
Trade/Device Name: Dade Behring Heparin Calibrator and Controls
Regulation Number: 21 CFR § 864.5425
Regulation Name: Multipurpose system for in vitro coagulation studies
Regulatory Class: II
Product Code: GIZ
Dated: October 22, 2004
Received: October 25, 2004

Dear Mr. Riesgo:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Robert L. Becker, Jr., M.D., Ph.D.
Director
Division of Immunology and Hematology Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K042941

Device Name: Dade Behring Heparin Calibrator and Controls

Indications for Use:

The Dade Behring Heparin Calibrator is an *in vitro* diagnostic product used to calibrate the Berichrom® Heparin assay for the measurement of unfractionated heparin. Dade Behring Heparin Controls are *in vitro* diagnostic products intended to be used as assayed, unfractionated heparin quality control materials for the Berichrom® Heparin assay.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Page 1 of 1

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K042941